RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0618

McNEIL CONSUMER PRC
FORT WASHINGTC

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Individual Safety Report
3032510-6-00

A. Patient information

1. Patient identifier	2. Age at time of event: / Date of birth:	3. Sex	4. Weight
Case 221 In confidence	or 25 yrs	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (x) death (mo/day/yr) none
- ( ) life-threatening
- (x) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
unknown	02/09/98

5. Describe event or problem

Case # 221 received from the [redacted] 1996 case fatality data.
See attached case report form provided by [redacted]

FEB 19 1998

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unknown acetaminophen product
#2 opiates

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 unknown dose, po	#1 unknown
#2 unknown dose, po	#2 unknown

4. Diagnosis for use (indication)

#1 unknown
#2 unknown

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2 unknown	#2 unknown

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

See attached case report form provided by [redacted]

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- (x) literature
- ( ) consumer
- (x) health professional
- ( ) user facility
- ( ) company represen...e
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 01/30/98

5.
(A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE	HEPATORENAL SYN
PROTHROMBIN INC	ANEMIA
COMA	CONVULSION
EDEMA LUNG	DEATH

9. Mfr. report number: 0929993A

E. Initial reporter

1. Name, address & phone #

[redacted] MD
[redacted] Centers
[redacted] Suite [redacted] Avenue
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

[redacted] FATALITY: 1996 [redacted]

Case Number:	**221**
Age:	25 yrs
Substances:	Acetaminophen opiates
Chronicity:	Unknown
Route:	Ingestion
Reason:	Unknown
Pre-Hospital Arrest?	No

A 25 year old female presented to an outlying hospital with a history of three days of abdominal pain that was being treated with dicyclomine, new onset lethargy, and acute onset hepato-renal failure. Her only other known medications were carisoprodol and fluoxetine that she took for chronic back pain. Approximately 16 hours after admission, the consulting nephrologist called the poison center, asking if this could be related to a toxic exposure. Her PT at this time was 42. She was anemic and her CPK, creatinine, bilirubin and liver enzymes were elevated. Her rapid urine drug screen was positive for opiates. She required dialysis for her renal failure. She was comatose, had had a seizure and was being mechanically ventilated. The toxicology fellow on call recommended that N-acetyl cysteine (NAC) be started orally or intravenously, in hope to salvage the liver, and recommended that a salicylate and an acetaminophen level be drawn. The acetaminophen level was 34; no acetaminophen was known to be given to the patient while in the hospital. The patient received NAC via nasogastric tube (NGT), with low NGT residuals. Further questioning of the patient's family revealed that the patient had a habit of taking excessive amounts of over-the-counter medications when she felt the medicines were not relieving her symptoms. The family did not feel that she had been suicidal. At 30 hours after hospital admission, the patients ammonia level was 168 and she was being treated with lactulose. At 60 hours after hospital admission the patient had pulmonary edema, a creatinine of 8.5, an elevated PT and a PTT of > 100. The toxicology fellow on call recommended high-flux dialysis and consideration of liver transplantation. At 90 hours after hospital admission, the patient died.